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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	22167-703	Total Pages	57
First Inventor or Application Identifier	Lytton A. Williams et al.		
Title	Method and Apparatus for Intervertebral Implant Anchorage		
Express Mail Label No.	EL473795841US		

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO:

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- ☒ Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original, and a duplicate for fee processing)
- ☒ Specification
(preferred arrangement set forth below) [Total Pages 26]
 - Descriptive title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed-Sponsored R&D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Detailed Description of the Drawings
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
- ☒ Drawing(s) (37CFR 1.152) [Total Sheets 20]
- ☒ Oath or Declaration [Total Pages 3]
 - ☐ Newly executed (original or copy)
 - ☒ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 17 completed)
 - ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).

- ☐ Microfiche Computer Program (Appendix)
- Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
 - ☐ Computer Readable Copy
 - ☐ Paper Copy (identical to computer copy)
 - ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

- ☐ Assignment Papers (cover sheet & document(s))
- ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney
(when there is an assignee)
- ☐ English Translation Document (if applicable)
- ☐ Information Disclosure Statement (IDS) PTO-1449 ☐ Copies of IDS Citations
- ☒ Preliminary Amendment
- ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
- ☒ Small Entity ☒ Statement filed in prior application,
Statement(s) Status still proper and desired
- ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
- ☒ Other: Express Mail Statement (37 CFR 1.10)

*NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.29)

- If a CONTINUING APPLICATION, check appropriate box and supply the requisite information below and in a preliminary amendment:
 - ☒ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No. 09/259,503

Prior application information: Examiner M. PriddyGroup/Art Unit: 3732

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

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Name (Print/Type)	David J. Weitz	Registration No. (Attorney/Agent)	38,362
Signature	<i>David J. Weitz</i>	Date	Aug 23, 2000

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**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) and 1.27(b) - INDEPENDENT INVENTOR**

Applicant or Patentee: Robert G. Watkins

Application or Patent No.: 09/259,503

Filed or Issued: February 26, 1999

For: METHOD AND APPARATUS FOR INTERVERTEBRAL IMPLANT ANCHORAGE

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Sections 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled:

METHOD AND APPARATUS FOR INTERVERTEBRAL IMPLANT ANCHORAGE

described in

☐ the specification filed herewith

☒ Application No. 09/259,503, filed February 2, 1999

☐ Patent No. _____, issued _____

I have not assigned, granted, conveyed, or licensed and am under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not be likewise classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below.

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☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, or any patent issuing thereon.

Date:

4/7/99

Signature:



Typed Name of Inventor: Robert G. Watkins

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PATENT
Attorney Docket No. 22167-703

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Lytton A. Williams et al.) Group Art Unit: Unknown
)
Application No. Unassigned) Examiner: Unknown
(Continuation of USSN: 09/259,503))
)
Filed: Herewith)
)
For: METHOD AND APPARATUS FOR)
INTERVERTEBRAL IMPLANT)
ANCHORAGE)

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-identified patent application on the merits, please amend the application as follows:

IN THE SPECIFICATION:

In the specification, page 1, prior to the heading "Field of the Invention", please insert the following:

--Relationship to Copending Applications

This application is a Continuation of U.S. Patent Application Serial No. 09/259,503, filed February 26, 1999, now U.S. Patent No. 6,113,638, which is incorporated herein by reference in its entirety.--

IN THE CLAIMS:

Please cancel claims 2-40 without prejudice or disclaimer. Originally filed claim 1 remains pending in the application.

REMARKS

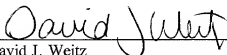
Entry of the above-identified Preliminary Amendment prior to examination on the merits is respectfully requested.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, or credit any overpayment to Deposit Account No. 23-2415 (Docket No. 22167-703).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

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Date: Aug 22, 2000

Method and Apparatus for Intervertebral Implant Anchorage

Inventor: Lytton A. Williams & Robert G. Watkins

FIELD OF THE INVENTION

5 The present invention relates to methods and devices for treating intervertebral disc diseases and more particularly to intervertebral prostheses for positioning in an intervertebral space to treat intervertebral disorders.

BACKGROUND OF THE INVENTION

10 Back pain remains a major public health problem, especially among aged people. Persistent and severe back pain often causes debility and disability, and such a pain is closely associated with intervertebral disc abnormalities of the spine.

15 The human spine is a flexible structure comprised of thirty-three vertebrae. Intervertebral discs separate and cushion adjacent vertebrae, and act as shock absorbers and allow bending between the vertebrae. An intervertebral disc comprises two major components: the nucleus pulposus and the annulus fibrosis. The nucleus pulposus is centrally located in the disc and occupies 25-40% of the disc's total cross-sectional area. The annulus fibrosis surrounds the nucleus pulposus and resist torsional and bending force applied to the disc. Vertebral end-plates separate the disc from the vertebra on either side of the disc.

20 Because of exertion, injury, illness, accident or abuse, one or more of the vertebrae and/or one or more discs may become damaged and malfunctioning. Specifically, disorders of the vertebrae and discs include but are not limited to 1) disruption of the disc annulus such as annular fissures; 2) chronic inflammation of the disc; 3) localized disc herniations with contained or escaped extrusions; and 4) relative instability of the vertebrae surrounding the disc.

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Various approaches have been developed to treat back pain. Minor back pain can be treated with medication and other non-invasive therapy. However, it is often necessary to remove at least a portion of the damaged and/or malfunctioning back component. For example, when a disc becomes ruptured, the ruptured disc may be surgically removed and the two vertebrae between the removed disc fuse together. In one approach, the end plates of two adjacent vertebra are fused posterior-laterally by screws. However, such posterior fusion with rigid end-plate fusion can be associated with pseudoarthrosis.

To promote fusion or arthrodesis across the intradiscal space, intervertebral implants are used to support and fuse together adjacent vertebrae by posterior-fusion or anterior grafting. For example, surgical prosthetic implant for vertebrae described in US Patent No. 5,827,328 include rigid annular plugs that have ridged faces to engage adjacent vertebrae to resist displacement and allow ingrowth of blood capillaries and packing of bone graft. These annular implants are usually made of biocompatible carbon fiber reinforced polymers, or traditional orthopaedic implant materials such as nickel, chromium, cobalt, stainless steel or titanium. The individual implants are internally grooved and are stacked against each other to form a unit between the two adjacent vertebrae. One of the disadvantages of these interlocked implants is that, the implants may not be stable enough to withstand rotation and may lead to implant loosening and failure of the prosthesis.

Another intervertebral fusion device described by Kozak, et al. (US Patent No. 5,397,364) includes an assembly of two lateral spacers and two central spacers, which defines a channel in the center of the fusion device for insertion of the bone graft material. The spacers are maintained in their configuration within the intradiscal space by screws threaded into a vertebra from the outside of the disc. A disadvantage of this device is a tendency for the anchoring screws to become dislodged.

SUMMARY OF THE INVENTION

An anchoring plate is provided for anchoring an intradiscal device to an end plate of a vertebra. The anchoring plate includes a plate member sized to be positioned within an intradiscal section between adjacent vertebrae and a plurality of anchoring elements extending from a surface of the plate member, each anchoring element including a distal portion capable of being introduced into the vertebra through the vertebral end plate. In one embodiment, at least one of the anchoring elements includes a lumen. The lumen allows ingrowth of the bone graft material through the lumen to the end-plate of the vertebra. The lumen preferably has a diameter between about 0.5mm - 9mm.

An implantable device for insertion into an intradiscal section between adjacent vertebrae is also provided which includes an anchor plate comprising of a plate member sized to be positioned within an intradiscal section between adjacent vertebrae and a plurality of anchoring elements extending from a surface of the plate member, each anchoring element including a distal portion capable of being introduced into an end plate of one of the adjacent vertebrae; and an intradiscal component coupled to the anchor plate. In one embodiment, the intradiscal component includes a spacer separating the anchor plate from the end plate of the other adjacent vertebra. In another embodiment, the intradiscal component includes a cage having a first side for positioning adjacent a first vertebra and a second side for positioning adjacent a second vertebra, the first side including a plurality of holes through which the anchoring elements on the anchor plate can be positioned, and the second side including at least one hollow bore for ingrowth of bone material. In yet another embodiment, the intradiscal component includes an artificial disc.

Another implantable device for insertion into an intradiscal section between adjacent vertebrae is provided which includes a first anchor

plate comprising a plate member sized to be positioned within an intradiscal section adjacent a first vertebrae and a plurality of anchoring elements extending from a surface of the plate member, each anchoring element including a distal portion capable of being introduced into an end plate of the first vertebra; a second anchor plate comprising a plate member sized to be positioned within an intradiscal section adjacent a second vertebrae and a plurality of anchoring elements extending from a surface of the plate member, each anchoring element including a distal portion capable of being introduced into an end plate of the second vertebra; and an intradiscal component coupled to the first and second anchor plates. In one embodiment, the intradiscal component includes a spacer separating the first anchor plate from the second anchor plate. In another embodiment, the intradiscal component includes a cage having a first side for positioning adjacent the first vertebra and a second side for positioning adjacent the second vertebra, the first and second sides each including a plurality of holes through which the anchoring elements on the first and second anchor plates can be positioned. In yet another embodiment, the intradiscal component includes an artificial disc.

A method is also provided for anchoring an implantable device within an intradiscal section between adjacent vertebrae which includes: creating a space between adjacent vertebrae;

inserting into the space created an intradiscal device comprising an anchor plate comprising a plate member sized to be positioned within the space and a plurality of anchoring elements extending from a surface of the plate member, each anchoring element including a distal portion capable of being introduced into an end plate of one of the adjacent vertebrae; and

causing the anchoring elements on the anchor plate to be introduced into the vertebrae through the vertebral end plate.

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In one embodiment according to the method, the anchoring elements are introduced into the vertebrae by applying a force to the anchor plate, anchor plate having a vector positioned entirely within the intradiscal space. In one variation, the force is applied to the anchor plate approximately perpendicular to a plane of the end plate,

In another embodiment, the anchoring elements are introduced into the vertebrae without rotating the anchor elements.

In yet another embodiment, the anchoring elements are introduced into the vertebrae without first creating one or more holes in the vertebrae for the anchoring elements.

In yet another embodiment, the implantable device includes an intradiscal component. Examples of intradiscal components include an intradiscal spacer, a cage, and an artificial disc.

In yet another embodiment, the implantable device includes first and second anchor plates, inserting including positioning the first anchor plate adjacent a first of the adjacent vertebra and positioning the second anchor plate adjacent a second of the adjacent vertebra, and causing including causing anchoring elements on the first anchor plate to be introduced into the first vertebra and causing anchoring elements on the second anchor plate to be introduced into the second vertebra.

In the apparatuses and methods of the present invention, the plate member preferably has a non-smooth surface so as to promote ingrowth of bone material on the surface. The plate member also preferably has at least one hollow bore through the plate to allow ingrowth of bone material through the plate to the end plate of the vertebra.

The anchoring elements can have a plurality of shapes including cone, cylinder, triangle, square, rectangle and other irregular shapes so long as the anchoring elements are capable of being introduced into an end plate of a vertebra. The anchoring elements can extend from the

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plate member substantially vertically, angularly or curved. The anchoring elements are preferably shaped so as to minimize the risk of splintering the vertebra by introducing the anchoring elements into the vertebra.

The apparatuses and methods of the present invention may be used for a variety of medical procedures in spine surgery. For example, the anchor plate may be used to secure an implant inserted between adjacent vertebrae, the implant including bone grafts, artificial annular plugs, compressible fusion material, artificial intravertebral disc or other prosthetic devices. The implantable device may be used to replace the damaged and/or malfunctioning intravertebral disc with an artificial disc attached to the anchor plate on the device, or to replace the whole vertebral body with an artificial vertebra which is biomechanically compatible to the spine. The implantable device can be customized to the individuals being treated. In one embodiment, the anchor plate has substantially the shape of a naturally-occurring intervertebral disc and the size of the patient's disc.

Additional advantages of the present invention are set forth in the description which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates an implantable device according to the present invention.

Figure 2 illustrates two hemi-implantable devices.

Figure 3A illustrates an implantable device having anchoring elements extending from one side of the device.

Figure 3B illustrates an implantable device having anchoring elements extending from opposing sides of the device.

Figure 4 illustrates an embodiment of an anchor plate

Figures 5A-D illustrate an implantable device having a cage.

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Figure 5A is a side view of the implantable device .

Figure 5B is a sagittal view the implantable device.

Figure 5C is a sagittal view of an anchor plate of the implantable device.

5 Figure 5D is a sagittal view of a spacer inside of the implantable device.

Figure 5E illustrates a disassembled implantable device with opposing anchor plates and sidewalls for maintaining a separation between the anchor plates.

10 Figure 5F illustrates side view of an assembled implantable device with opposing anchor plates and sidewalls for maintaining a separation between the anchor plates.

Figure 5G illustrates another side view of an assembled implantable device with opposing anchor plates and sidewalls for maintaining a separation between the anchor plates.

15 Figure 6 illustrates an implantable device containing an artificial intervertebral disc.

Figures 7 A-E illustrate assembly of an implantable device.

20 Figure 7A is a frontal view of the assembly of an implantable device.

Figure 7B is a side view of the assembly of an implantable device.

Figure 7C illustrates the assembled implantable device.

Figure 7D is a rear view of the assembled implantable device.

25 Figure 7E is a side view of the assembled implantable device.

Figure 7F illustrates assembly of the implantable device illustrated in Figures 5A-D.

Figure 8A illustrates an implantable device of Figure 7A-E inserted in an intradiscal space prior to extension of anchoring elements.

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Figure 8B illustrates the implantable device of Figure 7A-E where the anchoring elements have been extended into the end plates of adjacent vertebrae.

Figures 9A-D illustrate a method for implanting an implantable device according to the present invention.

Figure 9A illustrates inserting a spacer between two adjacent vertebrae.

Figure 9B illustrates putting a guide over the spacer.

Figure 9C illustrates inserting an implantable device into the guide.

Figure 9D illustrates using a wedge spreader to introduce anchoring elements into the end plate of the vertebra.

Figure 10 illustrates an example of a guide used in the method described in Figures 9A-D.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention relates to devices which may be anchored to vertebrae of the spine by introducing anchoring elements through an end plate of the vertebrae. In particular, an anchoring plate, which comprises a plurality of anchoring elements such as spikes or prongs extending from the plate, is provided for anchoring an intradiscal device to an end plate of a vertebra. By securing the anchor plate to an end plate of the vertebra, a surgeon operating on a patient's spine can attach a variety of intradiscal components to the anchor plates. The secured anchorage and support provided by the apparatus of the present invention prevents loosening of the apparatus and enhances the fusion of the adjacent vertebrae.

A variety of intradiscal components can be incorporated into the apparatus of the present invention. In one embodiment, the intradiscal component includes a cage within which the anchor plate is contained.

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Bone graft material can be filled into the cage which is attached to and stabilized by the anchor plate on an end plate of a vertebra, thereby promoting bone ingrowth through the holes on the cage. Alternatively, an artificial intervertebral disc can be included in the apparatus.

It should be noted that other intervertebral fusion devices may also be attached to the anchor plate for restoring or maintaining the normal geometry of the intradiscal space, such as disc height and sagittal angle. Moreover, an artificial vertebral body which is biomechanically compatible with the spine may be attached to the anchor plate to replace a damaged vertebra and restore normal functions to the spine.

One embodiment of the invention is illustrated in Figure 1, showing a frontal view of an implantable device 10 inserted between two adjacent vertebrae L4 and L5. In this embodiment, the implantable device 10 includes a first anchor plate 12, a second anchor plate 14 and an intradiscal component 16. Each of the first and second anchor plates includes a plate member 18 and a plurality of anchoring elements 20 extending from a surface 11 of the plate member 18. The anchoring elements 20 on each of the anchor plates 12 and 14 are introduced into vertebrae L4 and L5 through end plates E4 and E5 of vertebrae L4 and L5, respectively. This embodiment of the implantable device has a size approximating the intradiscal space between adjacent vertebrae. This device is particularly suitable for positioning via an anterior approach. Because intervertebral discs are located in front of the spine and anterior to the spinal cord 15, prosthetic operations such as disc replacement through an anterior approach eliminates the need to remove or retract nerve, thus reducing the risk of nerve injury.

Alternatively, the implantable device according to the present invention may also be sized to a hemicycle or hemioval. As illustrated in Figure 2, two hemioval implantable devices 30 and 32 can be used to

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approximate the intradiscal space and conform with the general outline
perimeter of the vertebrae. Such an implantable device with a hemioval
size allows better access to the posterior portion of the spine when the
devices are implanted through a posterior approach. For example, the
5 first hemi- device 30 can be inserted into and fill in half of the intradiscal
space without colliding with the spinal core 15, then followed by placing
the second hemi- implantable device 32 to fill in the other half of the
intradiscal space. Similar to the implantable device 10 illustrated in
Figure 1, the anchoring elements on the hemi- implantable device are
10 introduced into the end plate E4 and E5 of the vertebrae L4 and L5,
respectively. Bone graft material or artificial disc can be put into the
device for posterior-lateral fusion or rigid posterior instrumentation.
Positioning the bone graft material between first and second anchor
plates 12, 14 to attain fusion and prevent the anchor plates from being
15 dislodged from the vertebrae.

In another embodiment, as illustrated in Figure 3A, the
implantable device 40 includes an anchor plate 42 and an intradiscal
component 44. The anchor plate 42 includes a plate member 46 and a
plurality of anchoring elements 48 extending from the plate member 46.
20 The anchoring elements 48 can be introduced into an end plate of a
vertebra by applying a force in a direction 45 approximately
perpendicular to the end plate, thereby securing the device 40 within an
intradiscal space. In this regard, the force applied to the anchoring
elements may have a vector positioned entirely within the intradiscal
25 space.

In yet another embodiment, as illustrated in Figure 3B, an
implantable device 50 includes a first anchor plate 52, a second anchor
plate 54 and an intradiscal component 56. Each of the first and second
anchor plates 52 and 54 includes a plate member 58 and a plurality of
30 anchoring elements 60 extending from the plate member 58. The

anchoring elements 60 on anchor plate 52 can be introduced into an end plate of a vertebra in directions 55, 57 approximately perpendicular to the end plates, thereby securing the device 50 within an intradiscal space between the two adjacent vertebrae.

5 An illustration of an embodiment of an anchor plate is illustrated in Figure 4. In this embodiment, the anchor plate 70 includes a plate member 72 and a plurality of anchoring elements 74 extending from a surface 71 of the plate member 72. It is preferred that a plate member 72 has at least one hollow bore or hole 75 through surface 71 and 73 of
10 the plate member 72 to allow bone ingrowth through the hole 75 to the end plate E4 of vertebra L4, thereby enhancing fusion of adjacent vertebrae. The hole 75 may be positioned such that the hole is adjacent nucleus pulposus N4 of the operative intravertebral disc when the device is positioned intervertebrally. The hole is preferably smaller than
15 and optionally as large as the nucleus pulposus N4. This positioning and sizing of the hole 75 allows fusion of bone graft material with a weaker portion of the vertebra known to be highly vascular and biological active.

The anchor plate 70 includes at least two anchoring elements 74 distributed on the surface 71 of the plate member 72. The anchor plate
20 may have any regular shape: round, square, rectangle, elliptical, or an irregular shape. The anchor plate is preferred to have a surface area between about 5mm² - 40mm²; and a thickness preferably between about 1mm - 10 mm, more preferably about 5mm.

25 The anchoring elements 74 are preferred to be sharp spikes having a cone, cylinder, square or rectangle shape. The height and width of the anchoring elements are preferably between about 0.5mm - 15mm, 0.3mm - 15 mm, respectively.

In a preferred embodiment, the anchoring element 74 includes a lumen 80. The lumen preferably has a diameter between about 0.5mm -
30 9mm. The lumen allows ingrowth of the bone graft material through the

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lumen to the end-plate of the vertebra. The lumen also facilitates entry of the anchoring element into the end plate without splintering the vertebra. The surface of the lumen is preferably rough.

5 The distal portion 77 of the anchoring element 74 may be straight or curved. The surface 79 of the anchoring element 12 is preferred to have a smooth outer surface to facilitate penetration of the element 74 into the end plate E4. In particular, the surface 79 of the anchoring element 74 is preferred not to have a thread for screwing the element 74 into the end plate E4.

10 The anchoring elements 74 may extend from the plate member 11 substantially vertically, angularly or curved. The direction of the force used to cause the anchoring elements to enter the vertebra will depend on the shape and angular positioning of the anchoring elements.

15 The materials used to construct the anchor plate and the implantable device are preferred to be able to endure the stresses and environment to which a vertebra implant is subjected. In addition, such materials should be biocompatible, and substantially chemically inert so as not to cause any detrimental effect to the patient in whom the device is implanted. The anchor plate and implantable device may be made of radiolucent material such as carbon fiber reinforced polymers known
20 commercially as "Peek" (polyetherether ketone) or "Ultrapek" (polyether ketone, ether ketone, ketone), polycarbonate, polypropylene, polyethylene and polysulfone plastics material filled with glass or carbon fibers, or traditional orthopaedic implant material such as nickel stainless steel, titanium alloy, heavy plastic polymer, ceramic, etc. One of ordinary
25 skill in the art will recognize other suitable materials, for example, a cobalt-chromium alloy or a titanium alloy having 4% vanadium and % aluminum, ceramic material such as aluminium oxide and zirconium oxide. The surface 71 of the anchor plate 70 is preferred to be rough to
30 potentiate bone ingrowth on the side of the plate contacting the end

plate E4 of the vertebra L4, thereby strengthening the anchorage to the end plate. The surface 73 of the anchor plate 70 may be porous coated or coated with hydroxyapatite or bioactive proteins (e.g. bone morphogenic protein) to promote bone ingrowth.

5 Figures 5A-D illustrate a preferred embodiment of an implantable device. As illustrated in Figure 5A, the implantable device 100 includes an intradiscal component---a cage 102, a first anchor plate 104 and a second anchor plate 106 contained within the cage 102. A plurality of anchoring elements 108 on each of the anchor plates 104 and 106
10 extend from the anchor plates and through holes 115 on the surfaces 111 and 113, respectively of the cage 102. The cage 102 includes intervertebral lateral channels 105 and frontal channels 107 which are adapted to receive bone graft material therein. In addition, channel 109
15 is configured to receive a screw therethrough for causing the anchoring elements 108 to be pushed into the end plates of adjacent vertebrae.

 Figure 5B is a sagittal view of the implantable device 100. The surface 111 of cage 102 contacts an end plate of a vertebra and is preferred to be porous and coated with hydroxyapatite or bone morphogenic protein to promote bone ingrowth. As illustrated, anchoring
20 elements 108 with lumen 101 extend through holes 115 in the cage 102.

 Figure 5C illustrates the first anchor plate 104 included in the implantable device 100. A plurality of anchoring elements 108 extend substantially vertically from a plate member 112. The anchor plate 104 have hollow bores 117 to form part of channel 103 and recessed
25 portion configured to be accommodated within the cage 102 and to receive force applied to introduce the anchoring elements 108 into the end plates of adjacent vertebrae.

 Figure 5D illustrates a spacer 116 included in the cage of the implantable device 100. The hollow bores 119 form part of the channels
30 103, 105, 107 and 109.

Figures 5E-G illustrate an alternate embodiment of an implantable device with opposing anchor plates and sidewalls for maintaining a separation between the anchor plates. Figure 5E illustrates the device disassembled with two opposing anchor plates 104, 106 and two sidewall support members 129A and 129B. The sidewall support members each include recessed grooves 131 for attaching the sidewall support members to the anchor plates.

Figures 5F and 5G illustrate side views of the device illustrated in Figure 5E once assembled. Assembly is achieved by attaching each sidewall support member to a side of the anchor plates. The device illustrated in Figures 5E-G have an advantage of being smaller than the devices illustrated in Figures 5A-5D since the sidewall spacers remove the need for the cage.

Figure 6 illustrates an embodiment of an artificial disc 120. As illustrated in Figure 6, oval-shaped nucleus 121 made of ceramic or stainless steel is housed inside of the cage 122. Anchoring elements 128 extend from the anchor plates 124 and 126 and can be introduced into the end plates of adjacent vertebrae, thereby replacing the damaged and/or malfunctioning disc with an artificial one.

Details of the assembly of an embodiment of an implantable device are illustrated in Figures 7A-C. According to this embodiment, the implantable device 130 includes a first anchor plate 132, a second anchor plate 134, and a cage comprising an upper cover 138 and a bottom plate 140 (Figure 7A). The first and second anchor plates 132 and 134 are adapted to fit into the cage with a portion of the plates flanked by two supporting members 146. The anchoring elements 142 on the anchor plate are positioned through the hole 141 on the upper cover 138 and bottom plate 140. As illustrated in Figure 7B showing a side view of the assembly, a wedge 144 is inserted between the upper cover 138 and bottom plate 140 of the cage 136. Through a channel

formed by holes 145 and 147, a fixation screw 146 can be used to drive the wedge 144 which pushes the anchor plates 132 and 134 toward end plates of adjacent vertebrae, thereby introducing the anchoring elements 142 into the end plates and securing the device 130 intradiscally.

Further, as illustrated in Figure 7C showing the assembled implantable device 130, there are also a plurality of holes 143 throughout the anchor plates, the upper cover 138 and the bottom plate 140 to allow bone ingrowth through the device 130 to enhance intervertebral fusion.

Figure 7F illustrates assembly of the implantable device illustrated in Figures 5A-D.

A method is also provided for anchoring an implantable device within an intradiscal section between adjacent vertebrae which includes: creating a space between adjacent vertebrae;

inserting into the space created an implantable device comprising an anchor plate comprising of a plate member sized to be positioned within the space and a plurality of anchoring elements extending from a surface of the plate member, each anchoring element including a distal portion capable of being introduced into an end plate of one of the adjacent vertebrae; and

causing the anchoring elements on the anchor plate to be introduced into the vertebrae through the vertebral end plate.

Another method is provided for anchoring an implantable device within an intradiscal section between adjacent vertebrae which includes:

creating a space between adjacent vertebrae; inserting into the space created an implantable device comprising

a first anchor plate comprising of a plate member sized to be positioned within the space and a plurality of anchoring elements extending from a surface of the plate member, each anchoring element

including a distal portion capable of being introduced into an end plate of one of the adjacent vertebrae;

a second anchor plate comprising of a plate member sized to be positioned within the space and a plurality of anchoring elements extending from a surface of the plate member, each anchoring element including a distal portion capable of being introduced into an end plate of one of the adjacent vertebrae; and

causing the anchoring elements on the first and second anchor plates to be introduced into the vertebrae through the vertebral end plate.

As illustrated in Figure 8A, the anchoring elements 142 of first (132) and second (134) anchor plates of an implantable device 130 illustrated in Figures 7A-E are introduced into the vertebrae by applying a force with fixation screws 146 to the anchor plates approximately perpendicular to a plane of the end plate such as E4 and E5 of vertebrae L4 and L5, respectively. Figure 8B shows that the implantable device 130 is anchored between the adjacent vertebrae L4 and L5 by the anchoring elements 142 penetrating vertebral end plates E4 and E5.

As also illustrated in Figures 8A and 8B, the anchoring elements 142 are introduced into the vertebrae L4 and L5 without rotating the anchor elements 142. Screwing an element into a vertebra can cause the vertebra to splinter.

As also illustrated in Figures 8A and 8B, the anchoring elements are introduced into the vertebrae without first creating one or more holes in the vertebrae for the anchoring elements.

In yet another embodiment according to the method, the implantable device includes an intradiscal component. Examples of intradiscal components include an intradiscal spacer, a cage, and an artificial disc.

In yet another embodiment according to the method, the implantable device includes first and second anchor plates, inserting including positioning the first anchor plate adjacent a first of the adjacent vertebra and positioning the second anchor plate adjacent a second of the adjacent vertebra, and causing including causing anchoring elements on the first anchor plate to be introduced into the first vertebra and causing anchoring elements on the second anchor plate to be introduced into the second vertebra.

Figures 9A-9C illustrate a method for introducing a device according to the present invention by an anterior approach. Figure 10 illustrates a guide employed in the method.

As illustrated in Figure 10, a guide 160 includes a sleeve 162 and at least two lips 164 that can be inserted intradisally to maintain the height of the disc space. The sleeve 162 is preferably cylindric with an elliptical cross section 167, and has multiple vents 161 and 163 for proper circulation of air. A replacement disc 168 can be introduced into the intradiscal space through the sleeve 162 in a direction 165 approximately along a longitudinal axis of the sleeve.

Figures 9A-D illustrate a method for implanting a device via anterior approach. As illustrated in Figure 9A, an intervertebral disc 180 to be replaced is accessed through a laparoscopic anterior approach. The disc 180 is exposed anteriorly, i.e. beneath the chest and abdomen of the patient. After the disc 180 to be removed has been identified, the disc is surgically removed. To prepare the adjacent vertebrae to receive the disc replacement 168, cartilage on the end plates of the adjacent vertebrae is removed by an instrument 181 following known procedures. Care should be taken not to violate the end plates. One or two spacers 172 are then inserted into the intradiscal space, with the adjacent vertebrae being separately distracted by a wedge so as to allow proper

location of the spacer 172. The spacer 172 also serves as a measurement of the height of the disc space.

As illustrated in Figure 9B, a guide 160 (described in regard to Figure 10) is put over the spacers 172 with the lips 164 of the sleeve 162 replacing the spacers 172. The spacers 172 are then removed from the disc space. As illustrated in Figure 9C, once the disc replacement guide sleeve 160 is properly positioned, an implantable device such as a replacement disc 168, is inserted through the sleeve 162 into the interdiscal space. As illustrated in Figure 9D, a wedge spreader 174 is then inserted into a channel 173 defined by the implantable device to distract the anchor plates 176 and introduce anchoring elements 178 on the anchor plates 176 into the end plates of the adjacent vertebrae.

While the present invention is disclosed by reference to the various embodiments and examples detailed above, it should be understood that these examples are intended in an illustrative rather than limiting sense, as it is contemplated that modifications will readily occur to those skilled in the art which are intended to fall within the scope of the present invention.

What is claimed is:

1. An anchor plate for anchoring an intradiscal device to an endplate of a vertebra, the anchor plate comprising:
a plate member sized to be positioned within an intradiscal section between adjacent vertebrae; and
a plurality of anchoring elements extending from a surface of the plate member, each anchoring element including a distal portion capable of being introduced into the vertebra through the vertebral end plate.
2. An anchor plate according to claim 1 wherein the anchor plate includes at least 3 anchoring elements.
3. An anchor plate according to claim 1 wherein the anchor plate has a non-smooth surface.
4. An anchor plate according to claim 1 wherein the anchor plate has at least one hollow bore.
5. An anchor plate according to claim 1 wherein at least one of the anchoring elements includes a lumen.
6. An anchor plate according to claim 1 wherein at least one of the anchoring elements includes a lumen at least 0.5 mm in diameter.
7. An anchor plate according to claim 1 wherein the anchoring elements extend substantially perpendicular from the anchor plate.

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1 8. An anchor plate according to claim 1 wherein the anchoring
2 elements extent angularly from the anchor plate.

1 9. An anchor plate according to claim 1 wherein the anchoring
2 elements have at least one curved distal end.

1 10. An anchor plate according to claim 1 wherein the anchoring
2 elements have a smooth outer surface.

1 11. An anchor plate according to claim 1 wherein the anchoring
2 elements do not include a thread for screwing the anchoring element
3 into the vertebral.

1 12. An implantable device for insertion into an intradiscal section
2 between adjacent vertebrae, the device comprising:
3 an anchor plate comprising a plate member sized to be
4 positioned within an intradiscal section between adjacent vertebra and a
5 plurality of anchoring elements extending from a surface of the plate
6 member, each anchoring element including a distal portion capable of
7 being introduced into an end plate of one of the adjacent vertebrae; and
8 an intradiscal component coupled to the anchor plate.

1 13. An implantable device according to claim 12 wherein the anchor
2 plate includes at least 3 anchoring elements.

1 14. An implantable device according to claim 12 wherein the anchor
2 plate has a non-smooth surface.

1 15. An implantable device according to claim 12 wherein the anchor
plate have at least one hollow bore.

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1 16. An implantable device according to claim 12 wherein at least one
2 of the anchoring elements includes a lumen.

1 17. An implantable device according to claim 12 wherein at least one
2 of the anchoring elements includes a lumen at least 0.5 mm in
3 diameter.

1 18. An implantable device according to claim 12 wherein the
2 anchoring elements extend substantially perpendicular from the anchor
3 plate.

1 19. An implantable device according to claim 12 wherein the
2 anchoring elements extend angularly from the anchor plate.

1 20. An implantable device according to claim 12 wherein the
2 anchoring elements have at least one curved distal end.

1 21. An implantable device according to claim 12 wherein the
2 anchoring elements have a smooth outer surface.

1 22. An implantable device according to claim 12 wherein the
2 anchoring elements do not include a thread for screwing the anchoring
3 element into the vertebral.

1 23. An implantable device according to claim 12 wherein the
2 intradiscal component includes a spacer.

1 24. An implantable device according to claim 12 wherein the
2 intradiscal component includes a cage having a first side for positioning
3 adjacent a first vertebra and a second side for positioning adjacent a

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second vertebra, the first side including a plurality of holes through which the anchoring elements on the anchor plate can be positioned, and the second side including at least one hollow bore.

25. An implantable device according to claim 12 wherein the intradiscal component includes an artificial disc.

26. An implantable device according to claim 12 further includes at least one channel.

27. An implantable device for insertion into an intradiscal space between adjacent vertebra, the device comprising:

- a first anchor plate comprising a plate member sized to be positioned within an intradiscal section between adjacent vertebra and a plurality of anchoring elements extending from a surface of the plate member, each anchoring element including a distal portion capable of being introduced into an end plate of one of the adjacent vertebrae;
- a second anchor plate comprising a plate member sized to be positioned within an intradiscal section between adjacent vertebra and a plurality of anchoring elements extending from a surface of the plate member, each anchoring element including a distal portion capable of being introduced into an end plate of one of the adjacent vertebrae; and
- an intradiscal component coupled to the first and second anchor plates.

28. An implantable device according to claim 27 wherein the intradiscal component includes a spacer.

29. An implantable device according to claim 27 wherein the intradiscal component includes a cage having a first side for positioning

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1 adjacent a first vertebra and a second side for positioning adjacent a
2 second vertebra, the first side including a plurality of holes through
3 which the anchoring elements on the first anchor plate can be
4 positioned, and the second side including a plurality of holes through
5 which the anchoring elements on the second anchor plate can be
6 positioned,

1 30. An implantable device according to claim 27 wherein the
2 intradiscal component includes an artificial disc.

1 31. An implantable device according to claim 27 wherein the device
2 further includes at least one channel.

1 32. A method for attaching an anchor plate to one of the end plates
2 of adjacent vertebrae, the method comprising:
3 creating a space between adjacent vertebrae;
4 inserting into the space created an anchor plate comprising a
5 plate member sized to be positioned within the space and a plurality of
6 anchoring elements extending from a surface of the plate member, each
7 anchoring element including a distal portion capable of being introduced
8 into an end plate of one of the adjacent vertebrae; and
9 causing the anchoring elements on the anchor plate to be
10 introduced into the vertebrae through the vertebral end plate.

1 33. A method according to claim 32 wherein at least one of the
2 anchoring elements includes a lumen.

1 34. A method according to claim 32 wherein the anchor plate
2 includes at least one hollow bore.

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1 35. A method according to claim 32 wherein causing the anchoring
2 elements to be introduced into the vertebrae is achieved by applying a
3 force to the anchor plate approximately perpendicular to a plane of the
4 end plate so as to cause the anchoring elements on the anchor plate to
5 be introduced into the vertebra through the vertebral end plate.

1 36. A method according to claim 32 wherein causing the anchoring
2 elements to be introduced into the vertebrae is achieved without rotating
3 the anchoring elements.

1 37. A method according to claim 32 wherein causing the anchoring
2 elements to be introduced into the vertebrae is achieved without first
3 creating one or more holes in the vertebrae for the anchoring elements.

1 38. A method for anchoring an implantable device within an
2 intradiscal section between adjacent vertebrae, the method comprising:
3 creating a space between adjacent vertebrae;
4 inserting into the space created an implantable device comprising
5 an anchor plate comprising a plate member sized to be positioned within
6 the space and a plurality of anchoring elements extending from a
7 surface of the plate member, each anchoring element including a distal
8 portion capable of being introduced into an end plate of one of the
9 adjacent vertebrae, and an intradiscal component coupled to the anchor
10 plate; and
11 causing the anchoring elements on the anchor plate to be
12 introduced into the vertebrae through the vertebral end plate.

1 39. A method for anchoring an implantable device within an
2 intradiscal section between adjacent vertebrae, the method comprising:
3 creating a space between the adjacent vertebrae;

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1 inserting into the space created an implantable device comprising
2 a first anchor plate comprising a plate member sized to be
3 positioned within the space and a plurality of anchoring elements
4 extending from a surface of the plate member, each anchoring
5 element including a distal portion capable of being introduced into
6 an end plate of one of the adjacent vertebrae,

7 a second anchor plate comprising a plate member sized to
8 be positioned within the space and a plurality of anchoring
9 elements extending from a surface of the plate member, each
10 anchoring element including a distal portion capable of being
11 introduced into an end plate of one of the adjacent vertebrae, and
12 an intradiscal component coupled to the first and second anchor -
13 plates; and

14 causing the anchoring elements on the first and second anchor
15 plates to be introduced into the adjacent vertebrae through each of the
16 vertebral end plates.

1 40. A method according to claim 39 wherein causing the anchoring
2 elements to be introduced into the vertebrae is achieved by
3 simultaneously extending the anchoring elements of the first and second
4 anchor plates into the vertebral end plates.

Method and Apparatus for Intervertebral Implant Anchorage

Inventor: Lytton A. Williams and Robert G. Watkins

5

ABSTRACT

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Methods and devices are provided for intervertebral implant anchorage. An implantable device for insertion into an intradiscal section between adjacent vertebrae is provided. The implantable device includes at least one anchor plate which comprises a plate member sized to be positioned within an intradiscal section between adjacent vertebrae and a plurality of anchoring elements extending from a surface of the plate member, each anchoring element including a distal - portion capable of being introduced into the vertebra through the vertebral end plate; and an intradiscal component coupled to the anchor plate.

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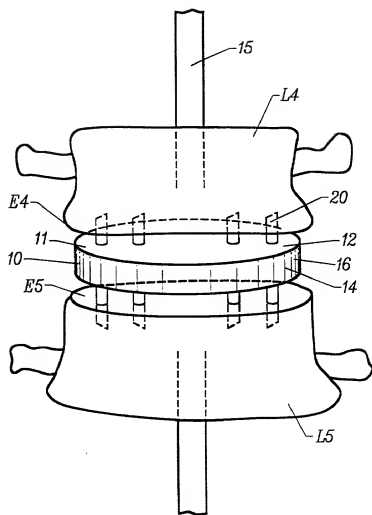


FIG. 1

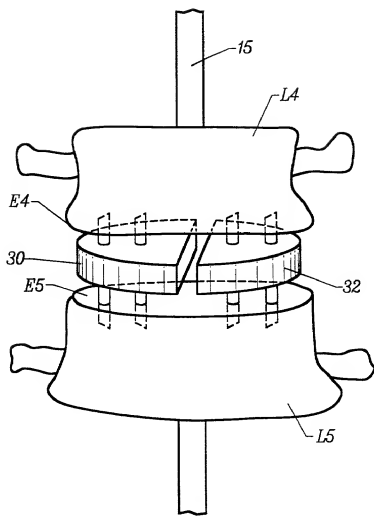


FIG. 2

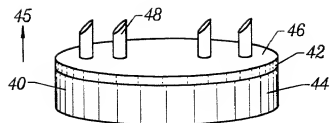


FIG. 3A

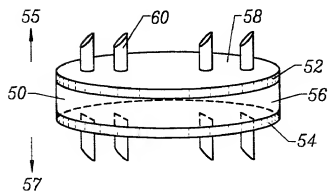


FIG. 3B

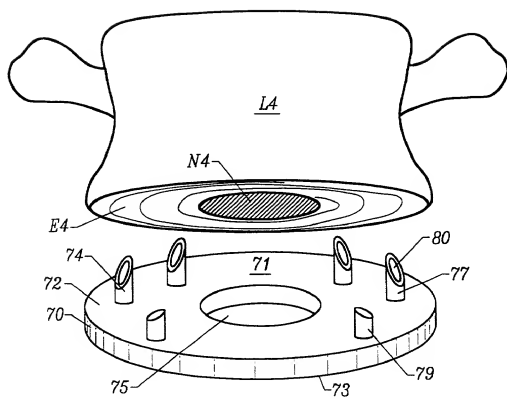


FIG. 4

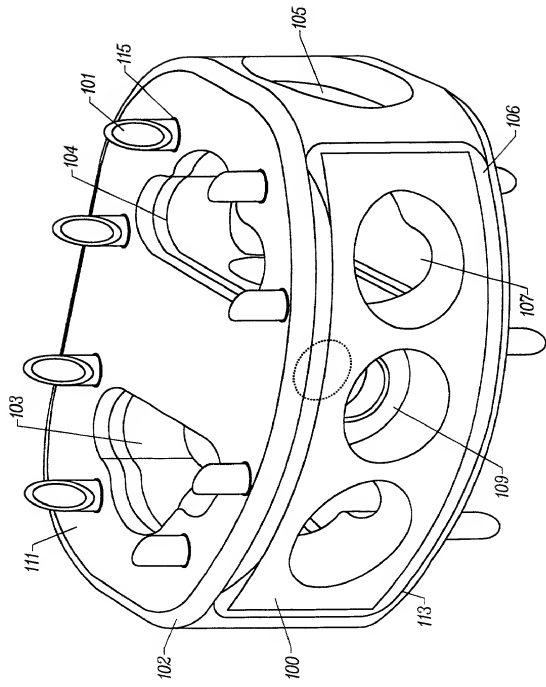


FIG. 5A

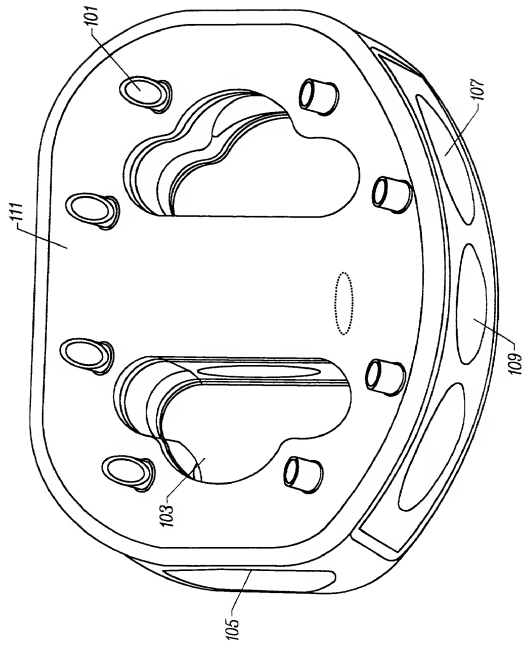


FIG. 5B

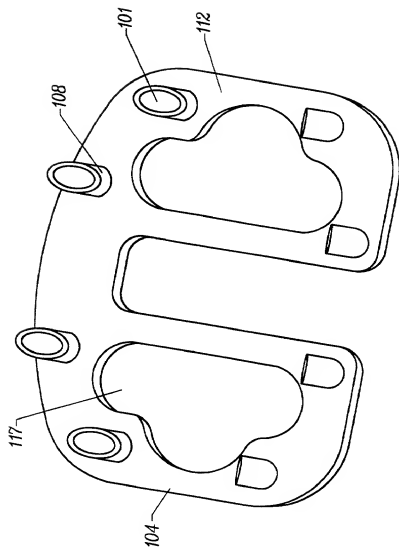


FIG. 5C

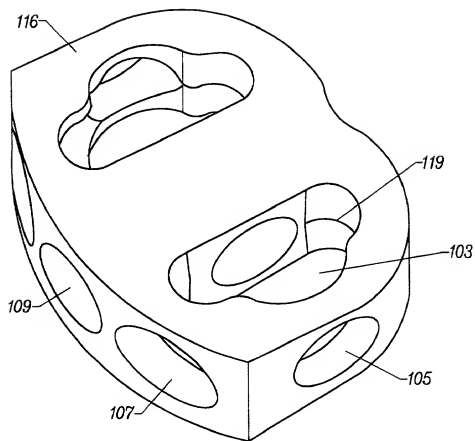


FIG. 5D

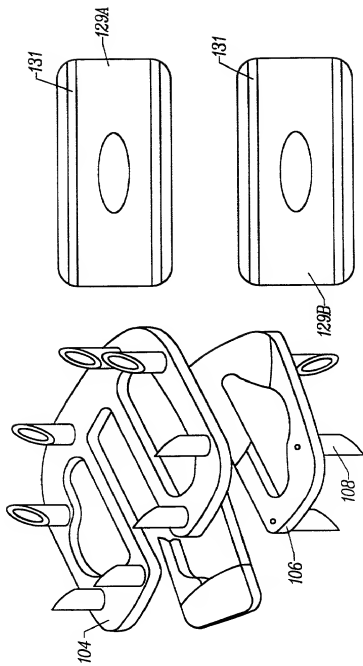


FIG. 5E

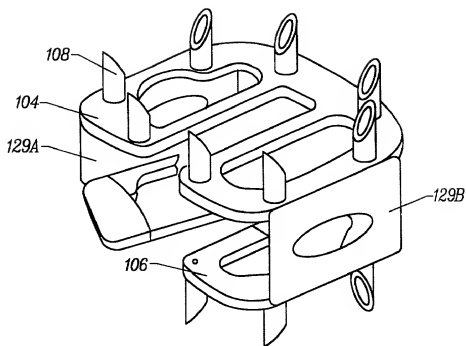


FIG. 5F

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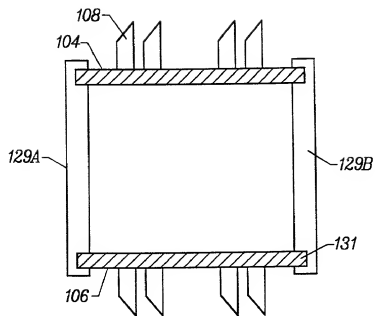


FIG. 5G

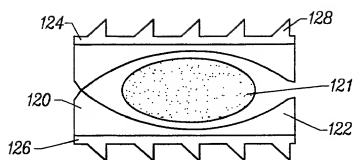


FIG. 6

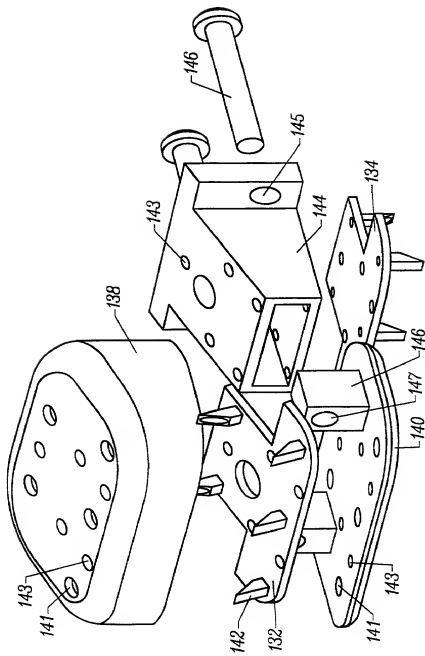


FIG. 7A

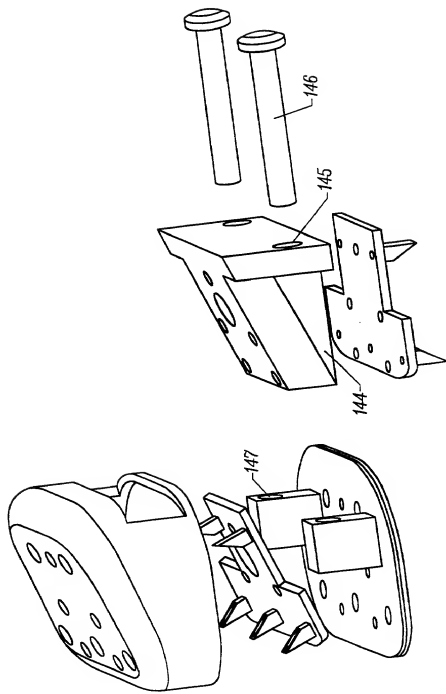


FIG. 7B

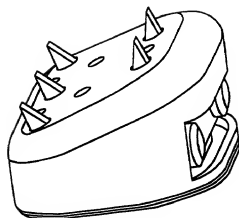


FIG. 7C

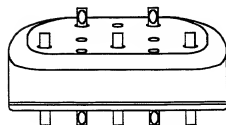


FIG. 7D

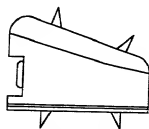


FIG. 7E

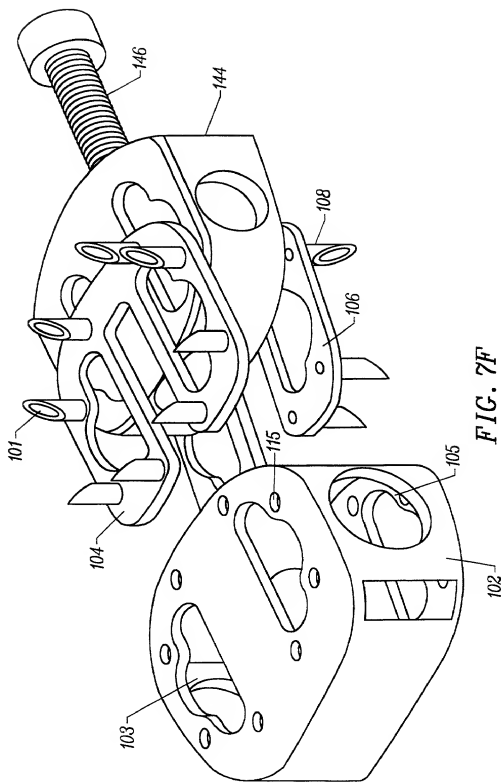
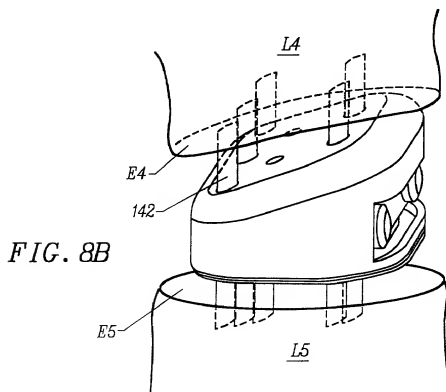
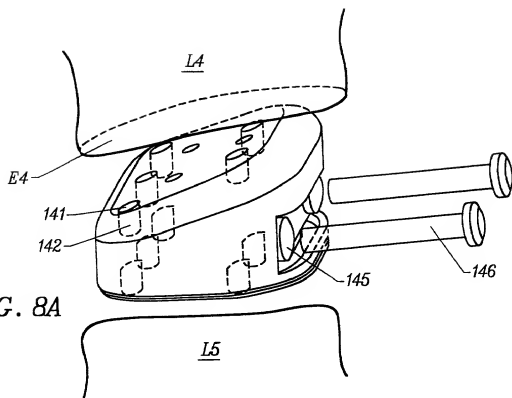


FIG. 7F



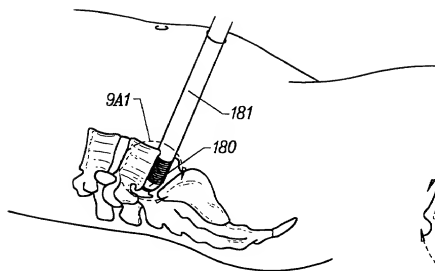


FIG. 9A

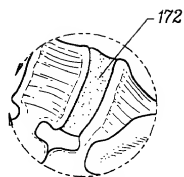


FIG. 9A1

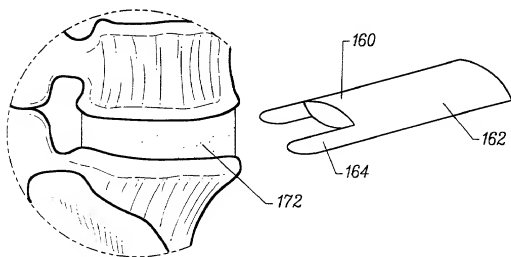


FIG. 9B

Figure 9C

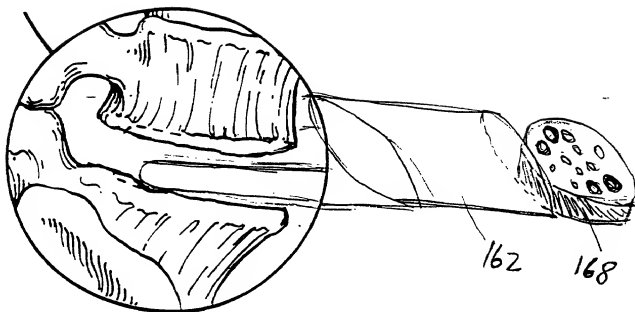
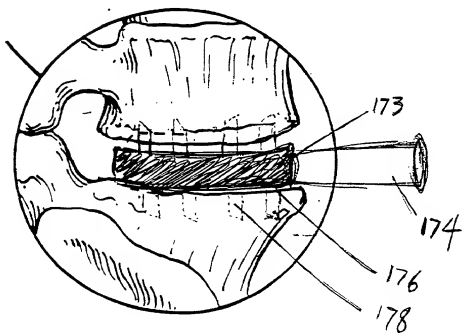


Figure 9D



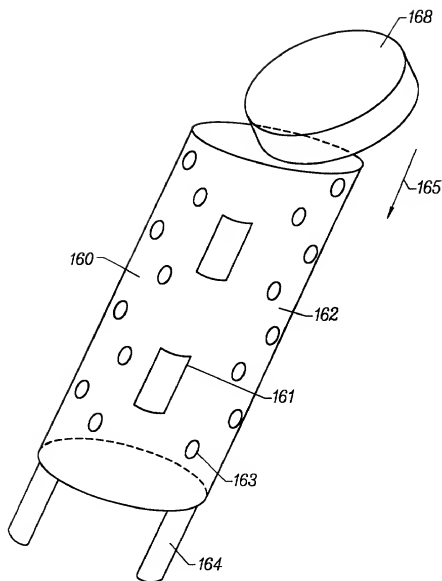


FIG. 10

COMBINED DECLARATION AND POWER OF ATTORNEY
FOR UTILITY PATENT APPLICATION

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHOD AND APPARATUS FOR INTERVERTEBRAL IMPLANT ANCHORAGE

the specification of which

_____ is attached hereto.

X was filed on February 26, 1999 as Application No. 09/259,503
and was amended on _____
(If Applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a) which states in relevant part: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section....The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98."

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate as indicated below and have also identified below any foreign application for patent or inventor's certificate on this invention having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

(Number)

(Country)

(Day/Month/Year Filed)

Yes

No

(Number)

(Country)

(Day/Month/Year Filed)

Yes

No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s), and under §119(e) of any United States provisional application(s), listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulation, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Patented, Pending, Abandoned)
(Application Serial No.)	(Filing Date)	(Patented, Pending, Abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith, and to file, prosecute and to transact all business in connection with international applications directed to said invention:

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John J. Bruckner	35,816
David J. Weitz	38,362
Kent R. Richardson	39,443
Charles C. Cary	36,764
Jeffrey D. Wheeler	39,066
David J. Abraham	39,554
U.P. Peter Eng	39,666
Henry Groth	39,696
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code, §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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4/7/99

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